SOP: Verification and Validation of Calibration Results Against Standards

This SOP details the **verification and validation of calibration results against standards**, including procedures for comparing calibration data with established standards, methods for assessing accuracy and precision, steps for documenting discrepancies, and guidelines for corrective actions. The purpose is to ensure that all calibration results are reliable, traceable, and compliant with regulatory requirements, thereby maintaining measurement integrity and quality control.

1. Purpose

To establish standardized procedures for the verification and validation of calibration results against recognized standards, ensuring accuracy, reliability, traceability, and compliance with regulatory requirements.

2. Scope

This procedure applies to all calibration activities and personnel involved in measurement processes where results are compared to established standards within the laboratory/organization.

3. Responsibilities

- **Calibration Personnel:** Perform calibrations, record results, and conduct initial verification and validation.
- **Quality Assurance (QA) Officer:** Review calibration documentation, validate processes, and oversee compliance.
- **Supervisors/Managers:** Approve corrective actions and ensure adherence to SOP requirements.

4. Definitions

Term	Definition
Calibration	The process of comparing measurements from an instrument to a known standard and adjusting as necessary.
Verification	Checking that calibration results conform to specified requirements or standards.
Validation	The confirmation that the calibration process and its results produce the intended outcome and meet all applicable standards.
Standard	A reference material or instrument with a known value, certified by an authoritative body.

5. Procedure

1. **Preparation**
    - Ensure all measurement standards and reference materials are valid, in date, and traceable to recognized national/international standards.
2. **Collection of Calibration Data**
    - Perform calibration according to the relevant SOP or manufacturer's instructions.
    - Record all calibration data accurately and completely.
3. **Verification Against Standards**
    - Compare calibration results to the specified acceptance criteria or tolerance limits defined by relevant standards or manufacturer specifications.
4. **Validation of Calibration Process**
    - Assess both accuracy (closeness to the standard value) and precision (repeatability of results).
    - Review environmental and procedural controls during calibration.

5. **Documentation**
    - Document all results, including measured values, acceptance criteria, verification status, and, if applicable, any deviations or discrepancies.
6. **Handling Discrepancies**
    - Document all discrepancies and notify QA or the responsible authority.
    - Initiate corrective action by identifying root cause and implementing corrective/preventive measures as per Section 7.
7. **Final Review & Approval**
    - QA reviews all documentation and validation records prior to final approval of calibration results.

6. Acceptance Criteria

- Calibration results must fall within the specified tolerance limits of the reference standards.
- Measurement uncertainty must be documented and remain within acceptable limits.
- All equipment and standards used must be certified, within calibration period, and traceable.

7. Corrective Actions

1. Immediately quarantine any instrument or measurement system with failing calibration results.
2. Investigate and identify the root cause of discrepancies or failures.
3. Repeat calibration after corrections, adjustments, or repairs as necessary.
4. Document corrective actions and outcomes in the calibration record.
5. Report persistent issues to higher management or regulatory authorities.

8. Records

- Calibration results and verification sheets
- Discrepancy and corrective action reports
- QA review and approval documentation
- Traceability certificates for every standard used

9. References

- ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories
- Applicable regulatory or customer-specific standards
- Manufacturer manuals and guidelines

10. Revision History

Revision	Date	Description	Approved By
1.0	2024-06-06	Initial release	QA Manager